DECLARATION OF INVENTORS UNDER 37 C.F.R. §1.131 Address to: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450		
	Application Number	09/630,340
	Confirmation Number	5593
	Filing Date	July 31, 2000
	First Named Inventor	Pan
	Examiner	Cross, Latoya
	Group Art	1743
	Attorney Docket No.	LIFE-009

Sir:

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6.

Respectfully submitted,

Date: _____ _____

Victor Pan

Date: 9/30/04 _____

John Lemke

Date: _____ _____

Harshad Patel

Date: _____ _____

Philip Cizdziel

Date: 9/30/04 _____

Robert Shartle

Attachment: Exhibit

INVENTION DISCLOSURE

3. Detailed Description of Invention

Purposes:

In an assay system that requires an external mechanism to draw the sample into the test strip, a method to accurately detect the presence of fluid sample at the sample application area is a crucial step in the test procedure. Once the sensor accurately detects the presence of fluid sample, this event allows the assay system to actuate the mechanism to draw the sample into the reaction zone.

The sample detection method must also guard against false detection, such as finger or other application device near the application area that can lead to premature actuation of the mechanism resulting in unreliable test result.

Description:

This method consists of a light source that illuminates the back-side of the test strip, and a sensor receives the reflected light from the test strip. The detection system is AC-modulated to provide immunity from the ambient noise and interference. When the test strip is inserted into the assay system, the reflectance readings increase and reach a steady state. When a finger or an application device is near the apparatus, the reflectance readings increase further. When the fluid sample is applied to the application area, the reflectance readings drop below the steady state values to indicate this condition (see Appendix). The system determines the sample application event by comparing percentage change of the signal with a threshold value.

From the percentage change in amplitude of the reflectance signal, the assay system can determine whether or not sufficient amount of sample is applied to the test strip. When the enough sample condition is met, the assay system triggers the actuator, and draws the sample into the reaction area.

The light source and detector can be chosen with spectral characteristics best suited to detect the sample and test strip.

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6. Date of First Disclosure to Others within the Company:

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9. First Commercial Use or Sale:

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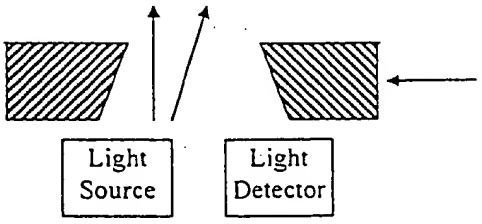
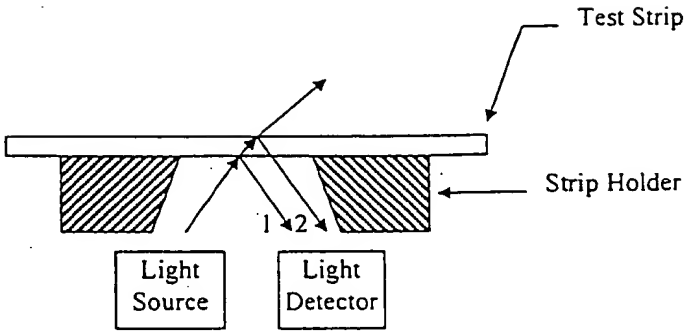
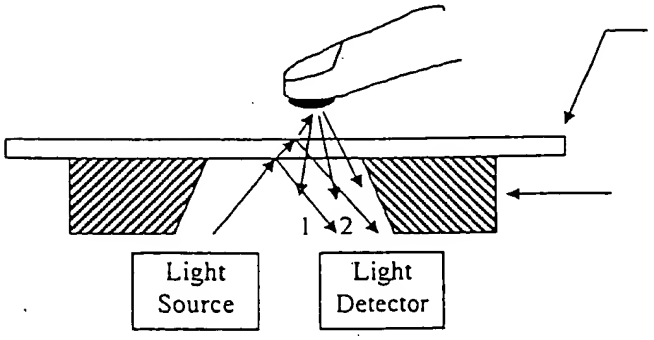
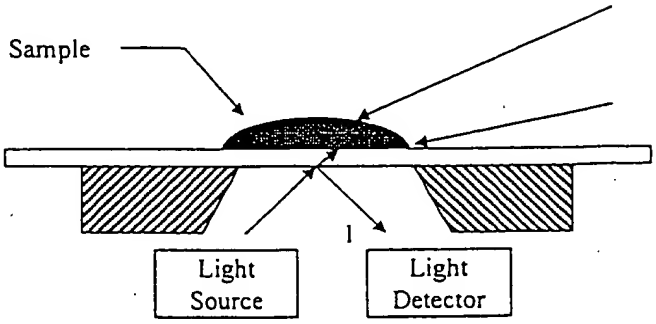


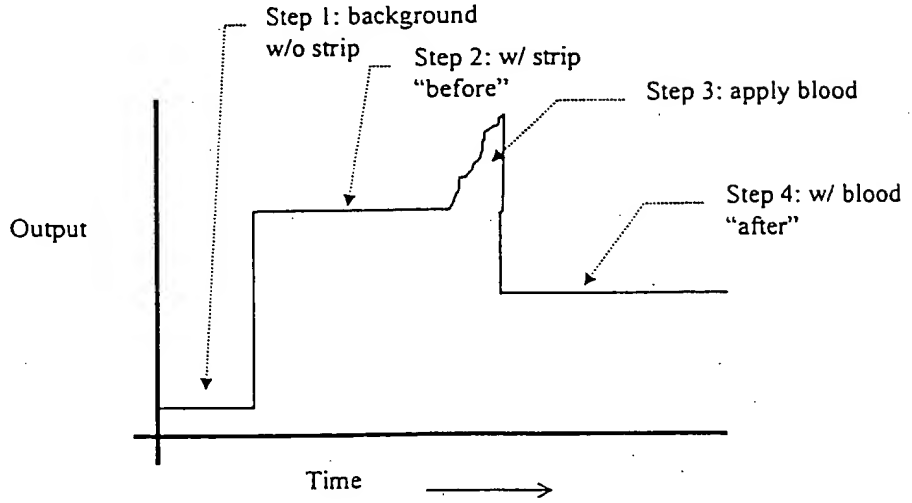




Step 4: Read signal after blood is applied



Typical Output Signal



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Date: _____ _____
Victor Pan

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John Lemke

Date: _____ _____
Harshad Patel

Date: 10-04-04 Philip Cizdziel
Philip Cizdziel

Date: _____ _____
Robert Shartle

Attachment: Exhibit

F:\DOCUMENT\life\009\1.131 declaration by inventors.doc

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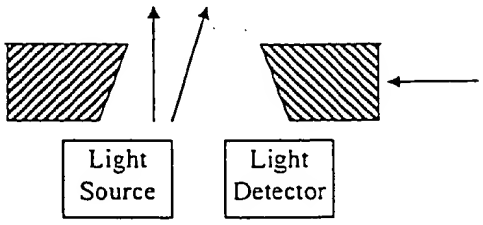

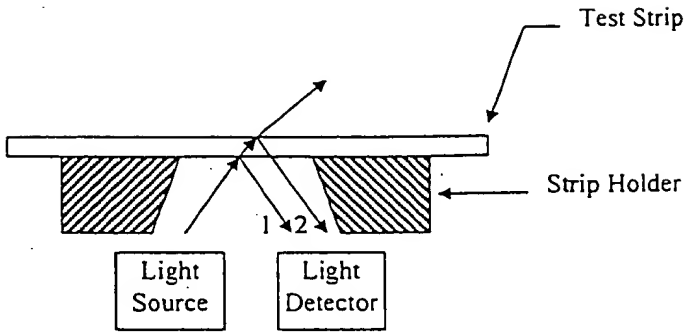

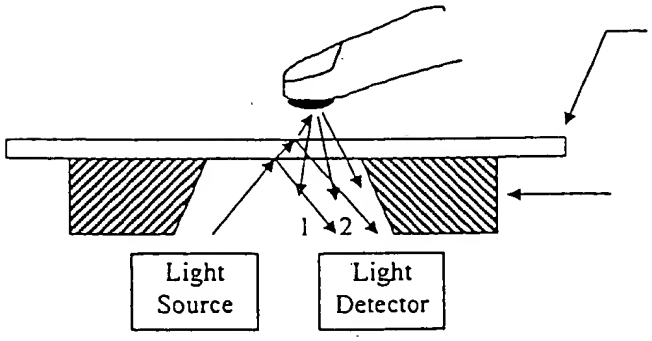

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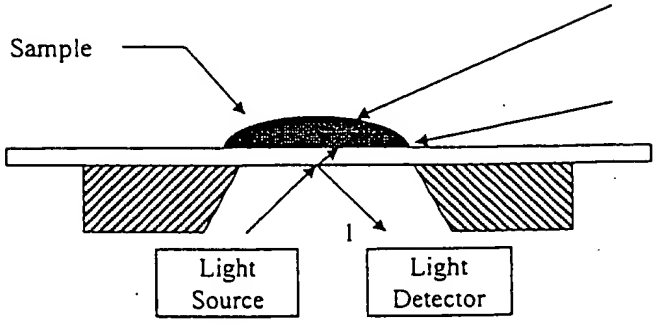
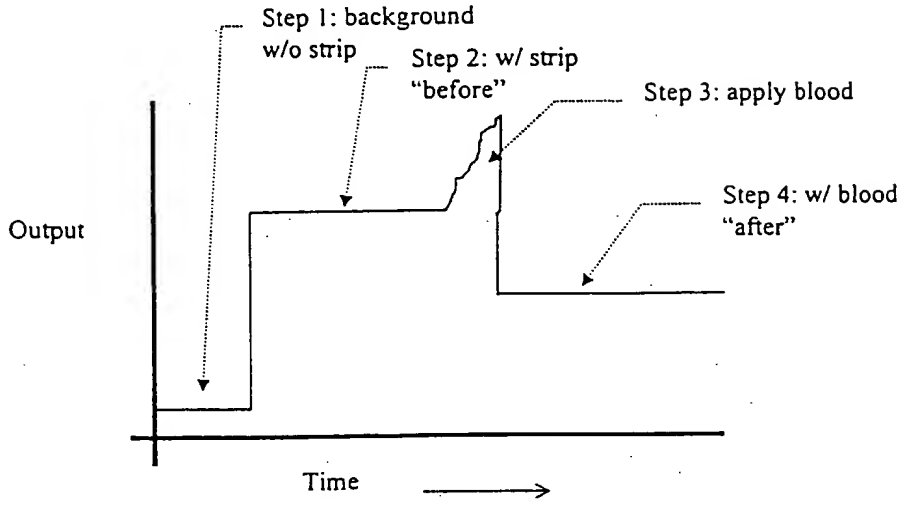


Typical Output Signal



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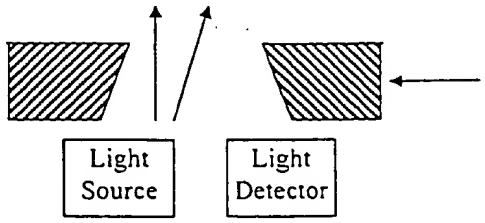

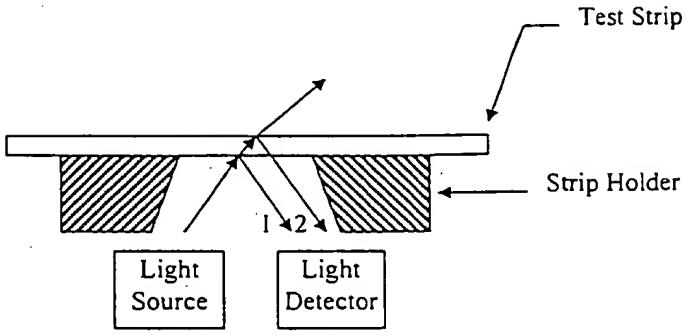

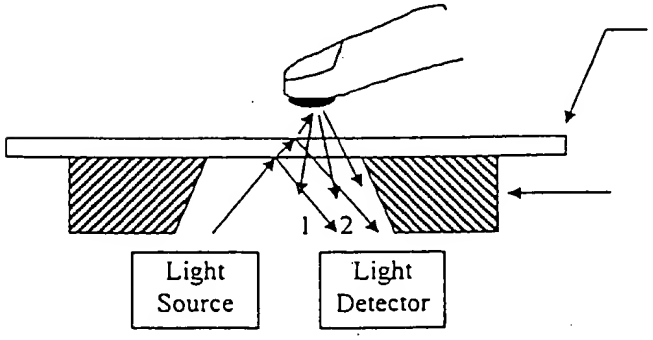

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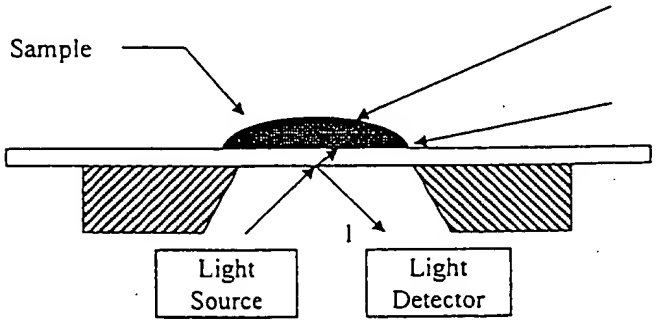
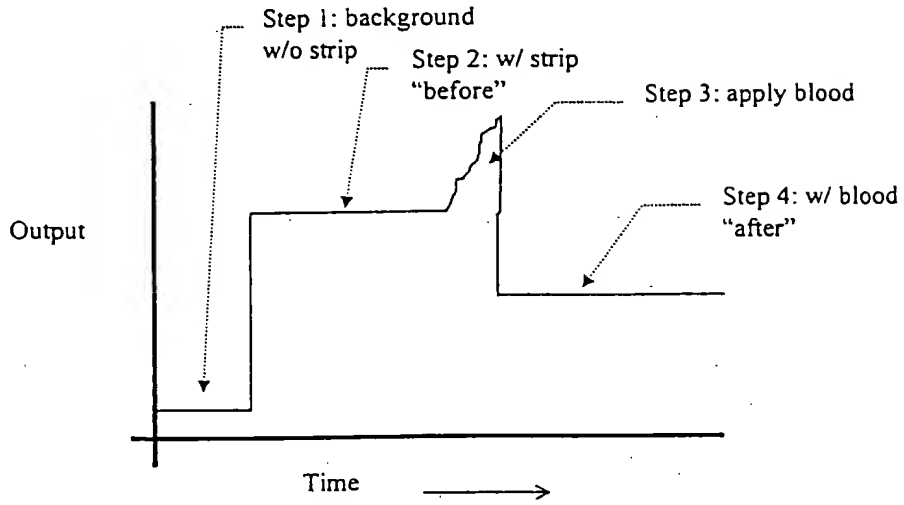


Typical Output Signal



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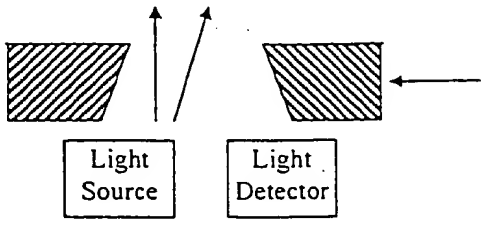

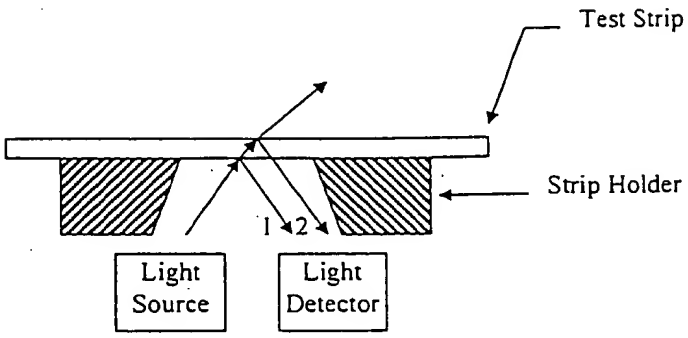

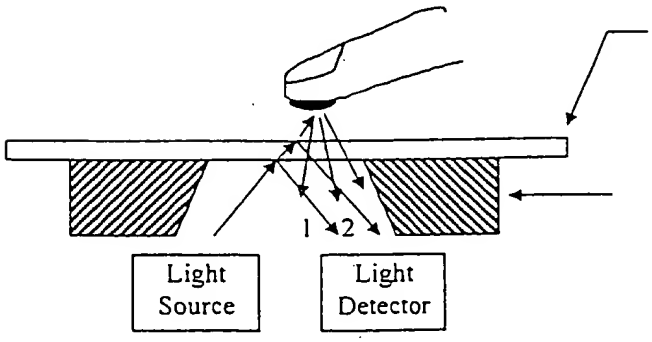

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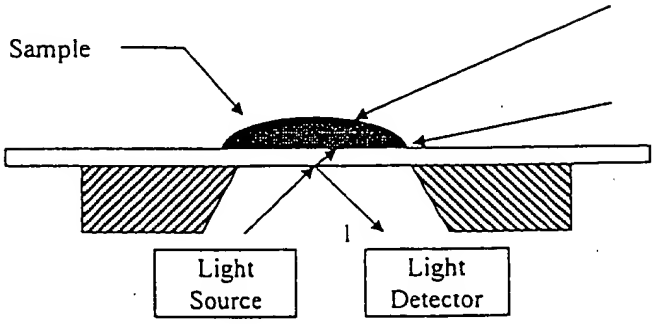

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